UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,054	04/01/2008	Christopher J Soares	0105US-UTL2	5466

44638 7590 12/16/2009

Intellectual Property Department
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121

EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	
MAIL DATE	**DELIVERY MODE**
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,054	SOARES ET AL.	
	Examiner	Art Unit	
	ZACHARY C. HOWARD	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 1/14/09 has been entered in full. Claims 12 and 13 are amended. New claims 20-32 are added.

Claims 1-32 are under consideration in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-13 and 18-32, drawn to an amylin family peptide.

Group II, claims 14-17, drawn to a method of treating a disease or disorder comprising administering to a subject an effective amount of an amylin family peptide.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I and II appears to be that they all relate to an amylin family peptide encompassed by claim 1 (the broadest of the claims of Group I). Claim 1 encompasses the following embodiment: a peptide comprising a loop region of calcitonin at the N-terminal end of the peptide, an alpha helix region of at least a portion of calcitonin, and a C-terminal tail of calcitonin, with the proviso that when the loop region is from a calcitonin and the alpha helix region is from a calcitonin, the last position of the C-terminal tail is not proline, hydroxyproline, homoserine or derivative of homoserine. The instant specification teaches that amino acids 1-7 of calcitonin are the loop region, amino acids 8-27 are the α helix region, and amino acids 27 or 28-32 are

the C-terminal region. Thus, claim 1 encompasses a calcitonin peptide wherein the final residue (proline 32) is mutated, but where the rest of the protein is unchanged.

Zaida et al (2002. Bone. 30(5): 655-663) teaches a modification of calcitonin that is "deletion of the C-terminal proline amide" (pg 656). In the absence of this proline, the final amino acid is different, e.g., alanine (human calcitonin) or threonine (salmon calcitonin; see amino acid sequences at pg 10 of the instant specification). Thus, Zaida et al teach a peptide comprising a loop region of calcitonin at the N-terminal end of the peptide, an alpha helix region of at least a portion of calcitonin, and a C-terminal tail of calcitonin, with the proviso that when the loop region is from a calcitonin and the alpha helix region is from a calcitonin, the last position of the C-terminal tail is not proline, hydroxyproline, homoserine or derivative of homoserine.

Therefore, the technical feature linking the inventions of Groups I and II does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Elections of species

Two elections of species are required as follows.

If Group I is elected, Applicants must elect species for elections (1) and (2).

If Group II is elected, Applicants must elect species for elections (1) and (3).

(1) Groups I and II each contain claims directed to more than one species of peptide of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

SEQ ID NO: 40-137.

The claims are deemed to correspond to the species in the following manner:

Claims 1-4 are generic.

Claims 5-32 encompass one or more of the species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each peptide consists of a different sequence of amino acids that results in a different structure for the peptide. Lack of unity is shown because these peptides lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) Group I contains claims directed to more than one species of linked molecule of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Polyethylene glycol polymer, polyamino acid and fatty acid.

The claims are deemed to correspond to the species in the following manner:

Claims 1-13 and 18-30 are generic.

Claims 31 and 32 recite each species as part of a Markush-type group.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each linked molecule is a molecule with a different structure. Lack of unity is shown because these linked molecules lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(3) Group II contains claims directed to more than one species of disease or disorder of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: eating disorders, insulin-resistance, obesity, abnormal postprandial hyperglycemia, Type I diabetes, Type II diabetes, gestational diabetes, Metabolic Syndrome, Dumping Syndrome, hypertension, dyslipidemia, cardiovascular disease, hyperlipidemia, sleep apnea, cancer, pulmonary hypertension, cholecystitis, and osteoarthritis.

The claims are deemed to correspond to the species in the following manner:

Claims 14-17 recite each species as part of a Markush-type group.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each disease or

disorder has a different etiology, symptoms, affected tissue, course and potential treatment. Lack of unity is shown because these diseases or disorders lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicants are required, in reply to this action, to elect a single species of (1) peptide (if Group I or II is elected), (2) linked molecule (if Group I is elected) and/or (3) disease or disorder (if Group II is elected) to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. Specifically, as part of such identification, Applicants must indicate which of claims 1-13 and 18-32 read on the elected species, including (1) whether the elected peptide is encompassed by formula I (SEQ ID NO: 34, claim 5), formula II (SEQ ID NO: 35, claim 8) and/or formula III (SEQ ID NO: 36, claim 10) and (2) whether the elected peptide is encompassed by one or both of the formulas recited in claims 18 and/or 19.

An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Bridget E Bunner/
Primary Examiner, Art Unit 1647